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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,938	01/29/2001	Thomas B. Carlson	DEKA:281US/MBW	9121
7590 11/05/2003			EXAMINER	
Robert E. Hanson Fulbright & Jaworski L.L.P. 600 Congress Avenue, Suite 2400 Austin, TX 78701			MEHTA, ASHWIN D	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/771,938	CARLSON, THOMAS B.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ashwin Mehta	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5,7-10,12,13 and 21 is/are allowed.
- 6) ☒ Claim(s) 2, 3, 6, 11, 14-20, 22-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The rejection of claim 21 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, is withdrawn upon further consideration.
3. The rejection of claims 24-26 under 35 U.S.C. 102/103 is withdrawn, upon further consideration.

### ***Claim Rejections - 35 USC § 112***

4. Claims 2, 3, 14, 16, 27, and 29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed April 15, 2003. Applicant traverses the rejection in the paper filed August 13, 2003. Applicant's arguments were fully considered but were not found persuasive. Claims 6, 11, 15-20, 22-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2: Applicant provides a definition of "population" as it appears in the on-line version of the Meriam Webster Dictionary (response, paragraph bridging pages 11-12;

Exhibit A). Applicant indicates that the relevant definition of “population” is “a body of persons or individuals having a quality or characteristic in common (response, paragraph bridging pages 8-9). However, the metes and bounds of the claim remain unclear. In their argument for the indefinite rejection of claim 3 (discussed below), Applicant indicates that a population of seed of I015036 can be non-uniform in that individual seeds of a population may not have the same size or shape. In this argument, Applicant appears to be implying that the population of claim 2 consists only of seed of the corn variety I015036, but that the population does not have to be essentially homogeneous because the seeds can have different sizes and shapes. However, in the paper submitted December 13, 2002, Applicant states that the population of claim 2 can include a small amount of other seed (page 5, 4<sup>th</sup> full paragraph). Applicant’s argument that the definition of “population” in claim 2 is as it appears in the Meriam Webster Dictionary is inconsistent with the previously presented argument. It is also inconsistent with the discussion on page 5, lines 15-22, about “essentially homogeneous populations” of inbred corn seed. That discussion indicates that such populations can be comprised of other types of seed other than the inbred seed.

Further, it is unclear exactly when a population can be defined as a population of I015036 seed and not a population of another seed variety. The paragraph bridging pages 5-6 of the specification states that inbred seed “generally” forms at least about 97% of total seed. The recitations “generally” and “at least about” leave the explanation open to encompass any other percentage of inbred seed. The very next sentence indicates that a population of inbred corn seed can contain 15% or less of inbred seed, and this would be indistinguishable from a small fraction, “generally” less than 2% and preferably less than 1% of inbred seed in a population of hybrid

seed. If a population contains a greater percentage of seed A than seed B, is this still defined as a population of seed B, rather than a population of seed A? The specification's discussion of "population" indicates that a population containing 85% of seed A and 15% of seed B can be defined as both a population of seed A and a population of seed B. It is also not clear what is meant by the term "generally" in the context of the definition for "population."

Regarding claim 3: Applicant argues that a population may be other than essentially homogeneous and still be a population. Applicant argues that the definition for "population," from the on-line version of the Meriam Webster Dictionary, is a body of individuals having a quality or characteristic in common, and that the definition for "homogeneous" from the same source is "of uniform composition or structure throughout." Applicant argues that, for example, a population of seed of corn variety I050136 could be of non-uniform size or shape, yet still have the common quality of being a seed that produces corn plant I015036 (response, paragraph bridging pages 8-9). However, the rejection is not based on such an issue, and was not raised in the previous Office actions. Applicant here appears to be redefining "essentially homogeneous," in that Applicant appears to be arguing that the recitation is referring to the non-uniform size and shape of individual I015036 plants. However, this is not consistent with how "essentially homogeneous" is discussed in the specification. It is noted that the discussion of "essentially homogeneous populations of inbred seed" on page 5, lines 15-19, indicates that such populations can have other types of seed. The rejection, currently and in previous Office actions, was not applied because of the non-uniform nature of individual I015036 seeds.

Regarding claim 14: Applicant again notes that a population of plants grown from the seed of I015036 could vary in size or other characteristics due to environmental or other

conditions, but still constitute a population of corn plants produced by growing seeds of corn variety I015036 (response, page 9, last full paragraph). As discussed above, Applicant appears to be redefining “essentially homogeneous.” Applicant’s argument is contrary to the specification, and the Office is not requiring the plants of the population of claim 14 to look exactly identical.

Regarding claims 16 and 27: Applicants argue that the claims contain a reference to a parent claim, contain a further limitation of the subject matter in the main claim, and incorporate all of the elements of the claim from which they depend (response, page 12, 2<sup>nd</sup> full paragraph). However, claims 16 and 27 do not further limit the subject matter of the main claim. The corn plants of the claims that claims 16 and 27 depend from do not comprise a nuclear or cytoplasmically-inherited gene conferring male sterility. A dependent product claim then cannot directly limit this plant by stating that it contains one of these genes. Further, the claims do not incorporate all of the elements of the claims from which they depend. For example, the plant of claim 15 is male fertile, and the plant of dependent claim 16 is not.

In claims 6 and 11: the recitation “in accordance with” renders the claims indefinite. The meaning of this recitation is not exactly clear, and makes the metes and bounds of the claims unclear.

In claims 15, 17, and 20: the recitation “capable of expressing” in line 1 of claim 15 and line 2 of claims 17 and 20 renders the claims indefinite. The recitation does not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed. It is suggested that the recitation in claim 15 be replaced with --having--, and in claim 20 with --has--.

Similarly, the recitation “is capable of regenerating” in line 2 of claim 17 renders it indefinite. It is suggested that the recitation “the tissue is capable of regenerating plants capable of expressing” be replaced with --plants, when regenerated from said tissue culture, have--.

In claim 18: the “derived from” in line 2 renders the claim indefinite. It is not clear how the cells are derived from the recited tissues. It is suggested that the term “derived” be deleted, or replaced with the term --isolated--.

In claim 22: the claim is improperly dependent on claim 21. Claim 22 recites a new process. However, to be properly dependent on claim 21, claim 22 should recite how the process of claim 21 is further limited. It is suggested that claim 22 be amended by deleting the recitation, “further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant”, and inserting the recitation, --, and said second parent corn plant is a distinct inbred corn plant-- in line 4 after “PTA-3225”.

In claim 28: the article “a” in the recitation “wherein the single locus was stably inserted into a corn genome” renders the claim indefinite. The recitation does not make clear if the genome is that of I015036 or that of a different corn plant.

In claim 30: the recitations, “yield enhancement,” “improved nutritional quality,” and enhanced yield stability” are relative terms that have no definite meaning, and make the metes and bounds of the claim unclear.

5. Claims 2, 3, 14, 24, 25, and 27-31 remain and claims 6 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed April 15, 2003 under item 8. Applicant traverses the rejection in the paper filed August 13, 2003. Applicant's arguments were fully considered but were not found persuasive.

Regarding claims 2, Applicant argues that a population of seed of the corn variety I015036 has been deposited with the ATCC. Applicant argues that claim 3 narrows the scope of claim 2, and is therefore described (response, page 13, 1<sup>st</sup> and 2<sup>nd</sup> full paragraphs). However, given the issues raised for claim 2 in the indefinite rejection discussed above, it is not clear that the population of claim 2 only consists of seed of corn variety I015036. As discussed above, the specification indicates that a population of an inbred corn seed can contain other types of seed. Further, in the paper submitted December 13, 2002, Applicant states that the population of claim 2 can include a small amount of other seed (page 5, 4<sup>th</sup> full paragraph). ATCC Accession No. PTA-3225 only describes seed of the corn variety I015036.

Regarding claim 14, Applicant argues the claim is similarly directed to an essentially homogeneous population of corn plants produced by growing seed of the corn variety I015036, and is therefore described (response, page 5, 2<sup>nd</sup> full paragraph). However, the specification indicates on page 5 that essentially homogeneous populations of an inbred corn seed can comprise other types of seed. This is inconsistent with Applicant's discussion of "essentially homogeneous populations" in the paper submitted August 13, 2003, as discussed above.

Regarding claims 24-25, Applicant argues that hybrid seeds and plants are described because they have I015036 as a parent and that they have inherited half of their genetic material from I015036 (response, page 14, 1<sup>st</sup> paragraph). The Examiner maintains that the claimed



hybrids will not have the same morphological and physiological characteristics as I015036. I015036 can be crossed with any other inbred corn plant to produce the claimed hybrids. The claimed hybrids then will express a combination of morphological and physiological characteristics that are different from each other, and which are also different from those expressed by I015036. That all hybrids will inherit half of their alleles from I015036 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids. The specification does not correlate any genes of I015036 with any of the traits that it expresses. Further, the claimed hybrids will inherit the other half of their genetic material from the other, unidentified and undescribed parent plant. The specification does not describe how those alleles inherited from I015036, or their products, will be affected by or interact with the alleles or their products inherited from the other parent. The expressed gene products will depend on the combination of the two alleles from each parent at each locus, whether the allele is dominant or recessive, and the epigenetic effects of other genes. The fact that any hybrid plant will inherit half of its alleles from I015036 then does not provide sufficient description of the morphological and physiological characteristics expressed by each and every hybrid plant.

Applicant also argues that the entire genetic contribution of corn plant I015036 is described by way of deposit of seed of I015036 with the ATCC, and believe that this represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants. In support of this argument, Applicant cites the decision of *Enzo Biochem, Inc. v. Gen-Probe Inc.*, for holding that a biological deposit constitutes a written description of the deposited material (response, page 14, 1<sup>st</sup> paragraph).

However, in the patent application considered in that decision, a function was correlated with the structure of the product that was deposited. Here, the functions of the claimed hybrid plants have not been correlated to the half of their genetic material originating from the deposited I015036 seed. The function of the plant grown from an I015036 seed is correlated with the structure of its entire genome, not just one half. Further, half of the alleles of the hybrid are inherited from the other parent. Therefore, the claimed hybrids do not have the same, complete genetic structure and function as that possessed by the deposited I015036 seed.

Applicant continues, citing the decision of *The Regents of the University of California v. Eli Lilly and Co.*, for noting that a name alone does not satisfy written description if structural features commonly possessed by members of the genus are not defined. Applicant argues that here, all of the members of the claimed genus of hybrids having I015036 as one parent share the identical feature of having the genetic complement of I015036 (response, paragraph bridging pages 14-15). However, the function of the product claimed in *Eli Lilly* was known. In the instant application, the specification does not describe the function of the claimed hybrids, and does not correlate the function of the hybrids with the structure of the I015036 genome. Furthermore, the genetic complement of the other unknown parent has not been described, and hence Applicant has not provided a written description of the multitude of possible hybrid corn plants that would result from crossing the deposited inbred I015036 with any and all other inbred or hybrid corn plants.

Applicant argues that the claimed F1 hybrid plants having I015036 as one parent will share the same genetic complement from I015036 and is readily identifiable by the genetic marker analysis in Tables 6 and 8. Applicant argues that hybrid corn plant 8012681 has the SSR

genetic marker profile of I015036 and includes the genetic markers from the second parent plant, and that this will be true for any other hybrid plant having I015036 as one parent, save for “an occasional difference at a locus due to spontaneous genetic rearrangements” (response, page 15, 1<sup>st</sup> full paragraph and page 18, 1<sup>st</sup> full paragraph). However, while all of the claimed hybrids will inherit the SSR marker profile of I015036, they will not inherit the same genetic markers from the other parent, as did hybrid 8012681, because they will have different parents. The SSR marker profiles of the other parents are not described. Further, the description of corn plant 8012681 does not describe the morphological and physiological traits of all other corn plants that can be produced by crossing I015036 to any other corn plant. One skilled in the art cannot identify all of the morphological and physiological characteristics of corn plant 8012681 that also definitely will be expressed by all other members of the genus, nor can one identify the characteristics that will be different. Further, while hybrid 8012681 has inherited the SSR marker profile of I015036, the specification does not describe the traits that are correlated with these markers. The traits expressed by 8012681 are not solely due to the presence of the alleles associated with the SSR markers, or the genetic contribution of I015036.

Applicant continues, arguing that the second plant that is used to make the hybrid is irrelevant. Because any second plant capable of reproduction may be used to make the hybrid, Applicant argues that the claimed hybrids cannot be said to lack written description for the second genetic complement (response, paragraph bridging pages 15-16 and page 16, 1<sup>st</sup> full paragraph). However, the genes that the hybrids inherit from I015036 will not solely determine the traits that are expressed. The traits, and therefore the functions of the hybrids, are determined by the interaction of the products of the genes inherited from I015036 with the products of the

genes inherited from the other parent. The contributions of the other parent cannot simply be disregarded.

Regarding the issue that information regarding the morphological and physiological traits of the hybrid plants has not been provided, Applicant argues that he has gone beyond the morphological and physiological traits by describing the claimed hybrid plants at the genetic level, and that a better description could not be made than at the genetic level, and that the entire genetic complement of parent plant I015036 is described by way of a seed deposit (response, page 17, 1<sup>st</sup> full paragraph and the paragraph bridging pages 17-18). However, as discussed above, the specification does not correlate any function of the claimed hybrids with this genetic information. The specification does not correlate any traits with any genes or molecular markers of I015036. Further, while I015036 seed has been deposited, none of the hybrid seeds, which produce plants having traits and functions that are different from I015036, have been deposited.

In response to the issue raised in the previous Office action, that other plants may share genetic marker data and that primer sequences are not described, Applicant argues that no effort was made to show that any substantial number of marker loci actually are shared by other plants (response, paragraph bridging pages 16-17). However, the specification shows that at least two other inbred corn plants share many of the same loci (see Table 6). Further, the specification does not explain why the SSR data of inbreds FBLL and FBMU were chosen for comparison with that of I015036 in Table 6, how related these inbreds are to I015036, and hence how useful the SSR markers are for distinguishing maize lines. Also, the specification does not mention

anything concerning the traits expressed by the FBLL and FBMU plants, and how similar those traits are to the combination of traits expressed by I015036.

Regarding claims drawn towards corn plant I015036 containing single locus conversions: Applicant appears to be arguing that the specification describes such plants, simply because the definition of “single locus converted plants” provided in the specification indicates that such plants possess essentially all of the desired morphological and physiological characteristics of plant I015036 in addition to the characteristics conferred by the single locus transferred (response, page 19, 1<sup>st</sup> full paragraph). However, the specification does not describe the characteristics expressed by the claimed plants. The specification does not describe any and all single locus conversion traits, nor the source of said traits. The traits conferred by the single locus may change one or more of the traits expressed by I015036. Further, the descriptions of plants that express “essentially” all of the “desired” characteristics of I015036 are not described. Further, the term “essentially” in the definition for “single locus converted plant” indicates that, in addition to the trait conferred by the single transferred locus, the plant does not have to express every one of the traits that the specification provides in its description of I015036. The definition also indicates that the plants only have to possess the “desired” characteristics of I015036, not all of them. The “desired,” as opposed to the “undesired,” traits are unknown. Backcross converted plants that do not have all of the morphological and physiological traits of I015036 are not described by the specification, or the deposit of I015036 seed.

Applicant cites *In re Gosteli* for indicating that the written description requirement does not require an applicant to describe exactly the subject matter claimed, but that the description must clearly allow persons of ordinary skill in the art to recognize what is claimed (response,

page 19, 1<sup>st</sup> full paragraph). However, the specification does not describe the traits expressed by all of the claimed plants, nor what set of traits are present in all of the claimed plants to allow persons of ordinary skill in the art to recognize the claimed plants. As discussed, the specification does not describe plants that express only some or “desired” traits that are expressed by I015036, or how to distinguish such plants from I015036. Further, single loci, for example those encoding a transcription factor, may affect one or more traits expressed by I015036. The claimed plant then would not express all of the traits of I015036. Such plants are not described by the specification.

Applicant continues, arguing that undiscovered genes are not claimed, and that the fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant, because it is the single locus conversion of corn plant I015036 that is claimed (response, page 20, 1<sup>st</sup> full paragraph). However, if a gene has not been discovered or isolated at the time the instant application was filed, Applicant cannot be in possession of a corn plant into which this gene was deliberately introduced.

Applicant argues, in response to the issue raised in the previous Office action that traits recited in the application have not been shown to be known in the art, that evidence submitted in the prior response showed numerous single locus traits. Applicant goes on to provide several examples (response, page 20, last full paragraph to the paragraph bridging pages 21-22). While the specification does cite references that describe numerous isolated genes, not all of the cited references actually teach that certain genes have been discovered or isolated. For example, the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability. If such single loci have not been discovered or isolated,

Applicant cannot be in possession of I015036 plants comprising this single locus conversion. The claims broadly encompass plant I015036 further comprising any single locus conversion, controlling any trait, including loci that have yet to be identified as independently controlling a trait. Applicant cannot be in possession of plants further comprising single locus conversions that have yet to be identified.

Applicant argues that, under the reasoning discussed in the previous Office action, any claim could be read to encompass subject matter yet to be invented and therefore not described. For example, a corn plant transformed with a particular gene would be invalid because it would encompass corn varieties yet to be discovered (response, page 20, 1<sup>st</sup> paragraph). In this example, however, there is only one genetic structure that is relevant, that of the particular gene, and only one function, determined by the properties of the product of that gene. A claim drawn towards a corn plant containing the gene is described, because the structure and function of the gene (presumably) is described. In the instant application, the invention encompasses corn seed I015036 and the plant produced by it. The deposit of the seed satisfies the written description requirement, and the functions of the plant are described in Tables 1-3. Another locus that is introduced into I015036 would change the traits, and therefore the functions, of I015036.

Applicant argues that techniques for the introduction of single locus traits by genetic transformation were well known (response, page 23, 1<sup>st</sup> full paragraph). That methods to produce genetically transformed corn plants existed at the time of the invention is, of course, not disputed. However, methods for producing a product do not describe the product itself.

Regarding claim 31: Applicant disagrees with the legal contention that products made in intermediate steps of method claims must be described, and argue that this is a misstatement of

the law (response, page 24, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs). Applicant continues, arguing that a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products, and that the starting materials must be provided, otherwise the process could not be completed (response, page 25, 1<sup>st</sup> full paragraph to page 26, 1<sup>st</sup> full paragraph). Applicants are directed to 64 Fed. Reg. 71427, 71428 (1999), comment No. 4, wherein application of the written description guidelines to methods have been adapted. The claimed methods require that further steps be conducted with the intermediate products. These products are not described, for the reasons discussed above. The process cannot be completed in the absence of the intermediate products. Hence, because the intermediate products are not described, the complete method necessarily is not described.

Concerning claims 6 and 11: written descriptions of each of the RFLP and isozyme markers of Table 6 and 7 are not provided. While the markers are named, this is not sufficient to describe them.

6. Claims 27, 29, and 30 remain and claim 28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed April 15, 2003 under item 9. Applicant traverses the rejection in the paper filed August 13, 2003. Applicant's arguments were fully considered but were not found persuasive.



Applicant argues that the cited references do not have any relevance to corn plants (response, paragraph bridging pages 26-27). However, the references do raise the issues of the effects linkage disequilibrium, linkage drag, and epistasis when one attempts to transfer a single locus from one plant variety to another. These effects are not limited to just the plants exemplified in the cited references, and Applicant does not explain why these issues are not a concern corn plants. Applicant also argues that the last Office action was incorrect in stating that information of the example of the conversion given in the specification was incomplete, and that the breeding history in that example has seven backcrosses (response, page 27, 1<sup>st</sup> full paragraph). However, there is no indication that all of the morphological and physiological traits of the DEKALB proprietary inbred corn plant were recovered, and that only one single locus was transferred from the donor parent. Further, the claims still encompass loci whose functions are unknown. One skilled in the art would not know how to use plants containing such loci. Single loci have also not been identified in the art for all of the traits listed in claim 30, as discussed above.

Claim 28 has been included in this rejection, as the recitation “wherein the single locus was stably inserted into a corn genome by transformation” (emphasis added), does not clearly indicate that it was plant I015036 that was transformed. The claim encompasses the embodiment that another corn plant was transformed, and that the single locus was introduced into I015036 by backcrossing.

Further, even if claim 28 were directed to plants in which a single locus were transformed directly into I015036, the specification does not enable transforming I015036 cells with all types of transgenes. As broadly interpreted, any type of transgene, encoding any product, could have

been introduced into I015036, including those that have not been isolated at the time the application was filed. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by “its physical or chemical properties” (e.g. a DNA sequence). Further, if the effect of transgene expression in I015036 is unknown, one skilled in the art would not know how to use the transformed plant. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Furthermore, the effects of transgene expression on the traits expressed by untransformed I015036 are unknown. The specification does not teach one how to use a transformed I015036 plant if all of the morphological and physiological traits of I015036 are not expressed. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

7. Claims 1, 5, 7-10, 12, 13, and 21 are allowed. Claims 2, 3, 6, 11, 14-20, and 22-31 are rejected.

#### ***Contact Information***

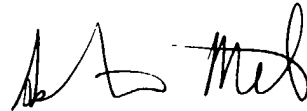
Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

October 29, 2003



Ashwin D. Mehta, Ph.D.  
Primary Examiner  
Art Unit 1638



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